120.016: Enforcement Policy and Procedures

(A) Enforcement Policy. The purpose of the enforcement program of the Agency is to promote and protect the radiological health and safety of the public, including employees' health and safety, and the environment by:

(1) Ensuring compliance with regulations and conditions of license;

(2) Obtaining prompt correction of violations and adverse quality conditions which may affect safety;

(3) Deterring future violations and occurrences of conditions adverse to quality; and,

(4) Encouraging improvement of licensee, registrant and vendor performance, and by example, that of industry, including the prompt identification and reporting of potential safety problems.

Consistent with the purpose of this program, prompt and vigorous enforcement action will be taken when dealing with all persons who do not comply with regulations. In no case will licensees who do not achieve and maintain adequate levels of protection be permitted to conduct licensed activities.

(B) Grounds for Suspension of a License or Certificate of Registration or Issuance of an Order to Immediately Cease Activity. In accordance with M.G.L. c. 111, § 5O, the Commissioner may summarily suspend a license or certificate of registration or order immediate cessation of an activity, without a prior hearing, whenever the Department finds that public health, safety or the environment would be threatened by delay in issuance of an order. A facility or person may not operate during the period of a suspension of his/its license or certificate of registration and may not conduct a prohibited activity after notification of an order requiring the immediate cessation of an activity. However, upon request by the licensee or registrant, a hearing shall be provided promptly after the issuance of such suspension order.

(C) Grounds for Denial, Modification, Limitation, Revocation or Refusal to Renew a License or Certificate of Registration.

(1) Specific Grounds. The Department may issue an order denying, revoking, modifying, limiting, or refusing to renew a license or certificate of registration sought or issued under 105 CMR 120.000 for any one of the following reasons:

(a) The applicant,licensee or registrant has failed to submit the information required for licensure or registration under 105 CMR 120.000.

(b) The applicant failed to meet the requirements for licensure or registration as specified in 105 CMR 120.000.

(c) The applicant, licensee or registrant is not suitable and responsible to operate a facility as required or provide the service as licensed or registered.

(d) The applicant, licensee or registrant has obtained or attempted to obtain or maintain a certificate of registration or license by fraud, misrepresentation, or by the submission of incorrect, false or misleading information.

(e) The applicant, licensee or registrant has failed to pay licensure and/or registration fees.

(f) The applicant, licensee or registrant has failed to pay civil penalties or criminal fines levied in accordance with of M.G.L. c. 111, § 5O or § 5P and/or 105 CMR 120.000.

(g) The applicant, licensee or registrant has:

1. failed to allow duly authorized agents of the Agency to conduct inspections; or

2. attempted to impede the work of duly authorized representatives of the Agency or the enforcement of any provisions of M.G.L. c. 111 §§ 5N through P or 105 CMR 120.000.

(h) The applicant, licensee or registrant has been convicted of, pleaded guilty to, or has, in a judicial proceeding, admitted facts sufficient for a finding that he/she is guilty of, any criminal violation relating directly or indirectly to his/her fitness to be licensed or registered under 105 CMR 120.000.

(i) The applicant, licensee or registrant has been the subject of proceedings which resulted in the suspension, denial, modification, limitation, or revocation of a similar license or certificate of registration or refusal of renewal of a similar license.

(j) The applicant, licensee or registrant has been the subject of proceedings which were ultimately resolved by settlement agreement but which were initiated to suspend, deny, modify, limit, or revoke or refuse renewal of a license, unless the Settlement Agreement contained provisions which either:

a. stated that the licensee, applicant or registrant was not guilty of the violations he/she/it was charged with or

b. provided that the charges or violations that were the subject of the Settlement Agreement or the Settlement Agreement itself cannot be used in whole or in part as the basis for any future licensing, registration or enforcement action by the Department.

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(k) The applicant, licensee or registrant has been disciplined in another jurisdiction in any way by a licensing authority for reasons substantially the same as those set forth herein.

(l) The applicant or licensee operated a facility after the expiration of the license.

(m) The applicant, licensee or registrant has failed to remedy or correct a cited violation by the date specified in the written notice from the Department under M.G.L. c. 111, § 5O or by the date specified in the plan of correction accepted or modified by the Department, unless the applicant, licensee or registrant demonstrates to the satisfaction of the Department that such failure was not due to neglect of duty and occurred despite his/her good faith attempt to make corrections by the specified time.

(n) The applicant or licensee has engaged in or aided in the falsification of test results.

(o) The applicant, licensee or registrant receives, possesses, uses, transfers, owns or operates or uses radioactive materials or machines which emit ionizing radiation in a manner which endangers public health, safety, or the environment.

(2) Other Grounds The Department reserves the right to deny, modify, limit revoke or refuse to review a license or certificate of registration for any other sufficient reason not listed in 105 CMR 120.016(C)(1) if it reasonably considers such action necessary to protect the public health, safety or the environment. In addition, nothing herein shall be deemed to limit the Department's authority to establish or recognize further general or specific grounds for discipline through rulemaking, adjudication, the issuance of polices or advisories or other similar means.

(D) Severity of Violations.

(1) Regulatory requirements have varying degrees of safety or environmental significance. Therefore, the relative importance of each violation must be identified as the first step in the enforcement process. Violations are categorized in terms of five levels of severity to show their relative importance within each of the following five activity areas:

(a) Health Physics;
(b) Transportation;
(c) Materials Operations;
(d) Miscellaneous Matters; and,
(e) Emergency Preparedness.

(2) Within each activity area, Severity Level I has been assigned to violations that are the most significant and Severity Level V to those that are the least significant. Severity Level I and II violations are of very significant regulatory concern. In general, violations that are included in these categories involve actual or high potential impact on the public. Severity Level III violations are cause for significant concern. Severity Level IV violations are less serious but are of more than minor concern; *i.e.* if left uncorrected, they could lead to a more serious concern. Severity Level V violations are of minor safety or environmental concern.

(3) Comparisons of significance between activity areas are inappropriate. For example, the immediacy of any hazard to the public associated with Severity Level I violations in Health Physics is not directly comparable to that associated with Severity Level I violations in Emergency Preparedness.

(4) While examples are provided in 105 CMR 120.019: *Appendix A* for determining the appropriate severity level for violations in each of the five activity areas, the examples are neither exhaustive nor controlling. These examples do not create new requirements. Each of the examples is predicated on a violation of an existing regulatory requirement. Each is designed to illustrate the significance which the Department places on a particular type of violation of regulatory requirements.

(5) In each case, the severity of a violation will be characterized at the level best suited to the significance of the particular violation. In some cases, violations may be evaluated in the aggregate and a single severity level assigned for a group of violations.

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(6) The severity level of a violation may be increased if the circumstances surrounding the matter involve careless disregard of requirements, deception, or other indication of willfulness. The term "willfulness" includes, but is not limited to, the deliberate violation of any provision of M.G.L. c. 111, §§ 3, 5M, 5N, 5O, and 5P or careless disregard of the requirements of M.G.L. c. 111, §§ 3, 5M, 5N, 5O, and 5P. Willfulness does not include acts which do not rise to the level of careless disregard, *e.g.* inadvertent clerical errors in a document submitted to the Agency. In determining the specific severity level of a violation involving willfulness, consideration will be given to such factors as the position of the person involved in the violation (*e.g.*, first-line supervisor or senior manager), the significance or any underlying violation, the intent of the violator (*i.e.* negligence not amounting to careless disregard, careless disregard, or deliberateness), and the economic advantage, if any, gained as a result of the violation. The relative weight given to each of these factors in arriving at the appropriate severity level will be dependent on the circumstances of the violation.

(7) The Agency expects licensees to provide complete, timely, and accurate information and reports. Accordingly, unless otherwise categorized in 105 CMR 120.019: *Appendix A* the severity level of a violation involving the failure to make a required report to the Agency will be based upon the significance of and the circumstances surrounding the matter that should have been reported. A licensee will not normally be cited for a failure to report a condition or event unless the licensee was actually aware of the condition or event which it failed to report. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the circumstances surrounding the matter.

(E) Enforcement Procedures.

(1)(a) Notice of Violation. Whenever the Agency finds upon inspection, investigation of a complaint or through information in its possession that an applicant, licensee or registrant is not in compliance with provisions of M.G.L. c. 111, §§ 5N through 5P or a regulation promulgated thereunder, the Agency shall notify the applicant, licensee or registrant of such violation or deficiency. The notice shall include a statement of the violations or deficiencies found, the provision of the law relied upon, and a reasonable period of time for correction. A violation or deficiency may result in denial, suspension, revocation or refusal to renew a license or certificate of registration; a modification or limitation of a license or certificate of registration; a cease and desist order; and/or the imposition of a civil penalty and/or criminal sanctions.

(b) Confirmatory Action Letters. The Agency may issue Confirmatory Action Letters confirming a licensee's, registrant's, or vendor's agreement to take certain actions to remove significant concerns about health and safety, safeguards, or the environment.

(2) Plan of Correction.

(a) The applicant, licensee or registrant shall within ten days of receipt of the notice, file with the Agency a written plan of correction. The plan shall clearly identify the licensee or registrant, state the date, reference the violation or deficiency cited, state specific corrective action(s) and timetable(s) and date(s) for completion for each deficiency cited, and shall be signed by either the applicant, licensee or registrant or his/her designee.

(b) The Agency may re-inspect a facility in order to determine whether the corrections have been made. If upon review of plan of correction and/or reinspection the Agency finds that the applicant, licensee or registrant is in compliance with 105 CMR 120.000 and/or that the applicant, licensee or registrant has submitted an acceptable plan of correction, the Agency shall notify the applicant, licensee or registrant of its findings of compliance and/or its acceptance or modification of the plan of correction.

(c) If upon review of plan of correction and/or reinspection the Agency finds the plan of correction is unacceptable, the Agency may request that the applicant, licensee or registrant amend and resubmit the plan of correction within five days of the date of notice or such other time as the Agency may specify for resubmission.

(d) If upon review of the plan of correction and/or reinspection the Agency determines that an applicant, licensee or registrant remains non-compliant with applicable laws and regulations regarding licensure, the Department may initiate enforcement procedures as set forth below.

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(3) Notice of Department's Intent to Issue an Order.

(a) Prior to the Department issuing an order to modify, limit,deny, revoke or refuse to renew a license, and/or to require a person to cease and desist any activity, and/or to impose civil penalties, the applicant, licensee or registrant shall be notified in writing of the grounds for the Department's action, the provision(s) of law relied upon, the amount of any civil penalty, and his/her right to request an adjudicatory proceeding and/or judicial review.

(b) If a license or certificate of registration is to be denied, modified, limited, revoked or refused renewal or if an activity is to be ceased or a civil penalty imposed by the Department, then the aggrieved applicant, licensee or registrant may request an adjudicatory hearing within 21 days of receipt of notification of the Department's Intent to Issue an Order. Said request shall be filed in accordance with Standard Adjudicatory Rules of Practice and Procedures, 801 CMR 1.01 *et seq*.

(4) Administrative Hearings: Procedure.

(a) Suspension of a License or Certificate of Registration or Issuance of an Order to Immediately Cease an Activity:

1. The Department shall give the licensee or registrant written notice stating the reason(s) for the suspension or issuance of an order to immediately cease an activity and the provisions of law relied upon. The suspension or order to immediately cease an activity shall take effect immediately upon issuance of the notice.

2. The Department shall provide for a hearing pursuant to 80l CMR 1.01 *et seq*. promptly after the issuance of an order of suspension or an order to immediately cease an activity.

3. In cases of suspension of a license or certificate of registration or issuance of an order to immediately cease an activity, the Hearing Officer shall determine whether the Department has proved by a preponderance of the evidence that there existed, immediately prior to or at the time of the suspension or cease and desist order, a threat to public health, safety or the environment.

4. In the event that the Department determines that the violation of state law or of 105 CMR 120.000 which posed a threat is corrected prior to the decision of the Hearing Officer, the Department may lift the suspension by giving written notice to the licensee or registrant.

(b) Denial, Modification, Limitation, Revocation, or Refusal to Renew a License or Certificate of Registration Based on Failure to File Reports or Pay Fees or Maintain Insurance: No hearing shall be afforded where denial, modification, limitation, revocation, suspension or refusal to review is based solely upon failure of the licensee or registrant to file timely reports, schedules or applications or to pay lawfully prescribed fees, or to maintain insurance coverage as required by any law or regulation.

(c) Denial, Modification, Limitation, Revocation or Refusal to Renew a License or Certificate of Registration; Orders to Cease an Activity; Civil Penalties:

1. All adjudicatory proceedings shall be conducted in accordance with M.G.L. c. 30A and the Standard Adjudicatory Rules of Practice and Procedure, 801 CMR 1.01 *et seq*.

2. Except for circumstances specified in 105 CMR 120.016(E)(4)(b), if the Department determines that a license or certificate of registration should be denied, modified, limited, revoked, or refused renewal, and/or that a facility should cease an activity, and/or that a civil penalty should be imposed, and if the Department notifies the applicant, licensee or registrant of its intended action, upon receipt of a Notice of Claim for an Adjudicatory Proceeding, the Department shall initiate a hearing pursuant to 801 CMR 1.01 *et seq*.

3. The Hearing Officer shall determine whether the Department has proved by a preponderance of the evidence that the license or certificate of registration should be denied, modified, limited, revoked or refused renewal; that an activity should be ceased; and/or that a civil penalty be imposed based on relevant facts as they existed at or prior to the time the Department initiated the hearing procedure.

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4. If the Hearing Officer finds any single ground for denial, modification, limitation, revocation, suspension, or refusal to renew a license or certificate of registration; for a cessation of an activity; and/or for imposition of a civil penalty, then the Hearing Officer shall render a recommended decision affirming the issuance of the Department's Order.

(d) Public Health Council and Judicial Review:

1. The recommended decision of a Hearing Officer in any adjudicatory proceeding conducted under 105 CMR 120.000 shall be reviewed by the Commissioner and the Public Health Council. Their decision upon this review shall constitute a final agency decision in an adjudicatory proceeding subject to judicial review pursuant to M.G.L. c. 30A § 14.

2. Any applicant, licensee or registrant that fails to exercise its right to an adjudicatory proceeding under 105 CMR 120.000 waives both its right to administrative review by the Commissioner and the Public Health Council and its right to judicial review pursuant to M.G.L. c. 30A § 14.

(F) Civil Penalties.

(1) If the Department determines, after a notice has been issued and an opportunity for a hearing has been provided, that a licensee, registrant or vendor has not complied with an order issued pursuant to M.G.L. c. 111 § 5O or with any provision of M.G.L. c. 111 §§ 5N through 5P or with any applicable rule, regulation, license or certificate of registration adopted or issued thereunder, the Department, in lieu of, or in addition to suspending, denying, modifying, limiting, revoking, or refusing renewal of a license or certificate of registration, may assess civil penalties in an amount not exceeding $100,000 per violation. Such civil penalty may be assessed whether or not the violation was willful.

(2) Generally, civil penalties are imposed for Severity Level I violations and if mitigating circumstances are absent, for Severity Level II violations. Civil penalties are considered for Severity Level III violations, and may be imposed for Severity Level IV violations that are similar to previous violations for which the licensee did not take effective corrective action.

(3) In applying this guidance for Severity Level IV violations, the Agency normally considers civil penalties only for similar Severity Level IV violations that occur after the date of the last inspection or within two years, whichever period is greater.

(4) Civil penalties will normally be assessed for known and conscious violations of the reporting requirements of 105 CMR 120.000 and for any willful violation of any Agency requirement including those at any severity level.

(5) Payment of civil penalties imposed under M.G.L. c. 111, § 5O shall be made by check, draft, or money order payable to the Commonwealth of Massachusetts, and mailed to: Radiation Control Program, 174 Portland Street, Boston, MA 02114.

(6) Factors in Determining the Amount of Penalty. In determining the amount of the civil penalty, the Department shall consider the following:

(a) The willfulness of the violation;

(b) The actual and potential danger to the public health or the environment;

(c) The actual or potential costs of such danger to the public health or the environment;

(d) The actual or potential damage or injury to the public health or environment;

(e) The actual and potential cost of such damage or injury;

(f) The actual or potential cost to the Commonwealth of enforcing provisions of 105 CMR 120.000;

(g) Whether the person being assessed the civil penalty did everything reasonable to prevent failure to, to come into compliance promptly, and to remedy and mitigate whatever harm might have been done as a result of the failure to comply;

(h) Whether the person being assessed the civil penalty has previously failed to comply with any order issued pursuant to M.G.L. c. 111, §§ 5N through 5P or any rule or regulation adopted hereunder;

(i) Whether imposition of a civil penalty is likely to deter future non-compliance;

(j) The financial condition of the person being assessed the civil penalty; and,

(k) The public interest.

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(G) Escalation of Enforcement Sanctions.

(1) The Department considers violations of Severity Levels I, II or III to be of significant regulatory concern. If serious violations occur, the Department will, where necessary, issue orders in conjunction with civil penalties to achieve immediate corrective actions and to deter further recurrence of serious violations. The Department carefully considers the circumstances of each case in selecting and applying the sanction(s) appropriate to the case in accordance with the criteria described in 105 CMR 120.016(D).

(2) Normally, the progression of enforcement actions for similar violations will be based on similar violations at an individual facility and not on similar violations under the same license. However, it should be noted that under some circumstances, *e.g.*, where there is common control over some facet of facility operations, similar violations may be charged even though the second violation occurred at a different facility or under a different license. For example, a health physics violation at one division of a dual unit hospital that repeats an earlier violation of the other division might be considered similar.

(H) Criminal Enforcement. The Department may elect to enforce any section of the regulations or provision of M.G.L. c. 111, § 5P by seeking to have criminal sanctions imposed. Any person who violates M.G.L. c. 111, § 5N or § 5O or any rule, regulation, license, registration, or order adopted or issued under said M.G.L. c. 111, § 5N or § 5O shall be fined not less than $100 nor more than $2,000, or be imprisoned for a period of not more than two years, or both. Any person who continues to violate the provisions of the aforementioned laws after due notice by the Department shall be fined not less than $1,000 nor more than $20,000 or be imprisoned for a period of not more than 20 years, or both. After due notice has been issued by the Department, each day of such violation shall constitute a separate offense.

(I) Judicial Enforcement. The Department may apply directly to the Supreme Judicial Court or Superior Court to enforce any provision of M.G.L. c. 111, §§ 5N through 5P and/or any rule or regulation, license, registration, or order adopted and issued thereunder by the Department. When a person is engaged in or about to engage in any act or practice which constitutes or will constitute a violation of such provision, rule, regulation, license, registration, or order, the Department may seek to restrain such act or practice or the use or occupation of premises or parts thereof or such other equitable relief as public health and safety requires.

(J) Nonexclusivity of Enforcement Procedures. None of the enforcement procedures contained in 105 CMR 120.000 are mutually exclusive. Any enforcement procedures may be invoked simultaneously if the situation so requires.

120.017: Severability

The provisions of 105 CMR 120.000 are severable. If any section, subsection, paragraph or provision is declared unconstitutional or invalid by a court of competent jurisdiction, the validity of the remaining provisions shall not be so affected.

120.018: Public Disclosure of Enforcement Actions

In accordance with M.G.L. c. 30A, the Administrative Procedures Act, all enforcement actions and licensees' responses are publicly available for inspection. In addition, press releases are generally issued for civil penalties related to violations at Severity Level I, II, or III. Press releases are issued at the time of the order or the proposed imposition of the civil penalty.

120.019: Appendix A -- Severity Categories

The following examples of severity levels are neither exhaustive nor controlling. They reflect only the seriousness of the violation and not the intent of the violator, the history of the violator, the amount necessary to deter future violations, or efforts to correct the violation.

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(A) Severity Level 1 -- Most Significant Violations.

(1) Health Physics.

(a) Single exposure of a worker in excess of 25 rems of radiation to the whole body, 150 rems to the skin of the whole body, or 375 rems to the feet, ankles, hands or forearms;

(b) Annual whole body exposure of a member of the public in excess of 2.5 rems of radiation;

(c) Release of radioactive material to an unrestricted area in excess of ten times the limits of 105 CMR 120.253;

(d) Disposal of licensed material in quantities or concentrations in excess of ten times the limits of 105 CMR 120.253;

(e) Exposure of a worker in restricted areas of ten times the limits of 105 CMR 120.212.

(2) Transportation.

(a) Annual whole body radiation exposure of a member of the public in excess of 0.5 rems of radiation; or,

(b) Breach of package integrity resulting in surface contamination or external radiation levels in excess of ten times the Agency limits.

(3) Materials Operations.

(a) Radiation levels, contamination levels, or releases that exceed ten times the limits specified in the license;

(b) A system designed to prevent or mitigate a serious safety event not being operable when actually required to perform its design function.

(4) Miscellaneous Matters.

(a) A Material False Statement (MFS)[1] in which the statement made was deliberately false;

(b) Falsification of records which the Agency requires be kept of significant information in which the records were deliberately falsified by or with the knowledge of management; or,

(c) A knowing and intentional failure to provide any notice required by 105 CMR 120.000.

(d) Possession of licensable quantities of radioactive material without a license, or loss of control of a source of radiation.

(e) Refusing authorized Agency personnel access to facilities, records and/or equipment to conduct inspections or investigations.

(5) Emergency Preparedness. In an emergency, licensee failure to promptly:

(a) correctly identify the event;

(b) make required notifications to responsible Federal, State, and local agencies; or

(c) respond to the event (*e.g.*, assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff).

(B) Severity Level II -- Very Significant Violations.

(1) Health Physics.

(a) Single exposure of a worker in excess of 5 rems of radiation to the whole body, 30 rems to the skin of the whole body or 75 rems to the feet, ankles, hands or forearms;

(b) Annual whole body exposure of a member of the public in excess of 0.5 rems of radiation;

(c) Release of radioactive material to an unrestricted area in excess of five times the limits of 105 CMR 120.222;

(d) Failure to make an immediate notification as required by 105 CMR 120.282(A), and (B);

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[1] In essence, a Material False Statement is a statement that is false by omission or commission and is relevant to the regulatory process. As can be seen in the examples, in determining the specific severity level of a violation involving material false statements or falsification of records, consideration will be given to such factors as the position of the person involved in the violation (*e.g.*, first line supervisor or senior manager), the significance of the information involved, and the intent of the violator (*i.e.*, negligence not amounting to careless disregard or deliberateness). The relative weight given to each of these factors will be dependent on the circumstances of the violation.

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(e) Disposal of license material in quantities or concentrations in excess of five times the limits of 105 CMR 120.253;

(f) Exposure of a worker in restricted areas in excess of five times the limits of 105 CMR 120.212.

(g) An x-ray system having a malfunction such that inadvertent exposures could occur *e.g.*, a system such that when the exposure switch is activated, not one but repeated exposures occur, or the timer fails to terminate exposure, or exposure initiated without utilizing the exposure switch.

(h) A fluoroscopic x-ray system with a tabletop entrance exposure rate of greater than or equal to 25 R/min. at the point where the center of the useful beam enters the patient, except:

a. During recording of fluoroscopic images; or,

b. When an optional high level control is activated.

(i) A fluoroscopic system such that the entire x-ray beam is not intercepted by the primary protective barrier; or,

(j) Therapy systems which exhibit excessive leakage and/or inoperable door interlocks, shutters, timers, *etc*.

(k) Therapy system, with improper operator/patient communication/observation.

(2) Transportation.

(a) Breach of package integrity resulting in surface contamination or external radiation levels in excess of Agency requirements;

(b) Surface contamination or external radiation levels in excess of five times Agency limits that did not result from a breach of package integrity; or,

(c) Failure to make required initial notifications associated with Severity Level I or II violations.

(3) Material Operations.

(a) Radiation levels, contamination levels, or releases that exceed five times the limits specified in the license; or,

(b) A system designed to prevent or mitigate a serious safety event being inoperable.

(4) Miscellaneous Matters.

(a) A MFS, or a reporting failure, involving information which, had it been available to the Agency and accurate at the time the information should have been submitted, would have resulted in regulatory action or would likely have resulted in the Agency seeking further information;

(b) A MFS in which the false statement was made with careless disregard.

(c) Deliberate falsification of records which the Agency requires be kept involving significant information; or,

(d) A failure to provide the notice required.

(e) Failure to register sources of radiation or services as required by 105 CMR 120.000.

(f) Action by management to discriminate against an employee for attempting to communicate or for actually communicating with the Agency.

(5) Emergency Preparedness. Licensee failure to meet or implement more than one emergency planning standard involving assessment or notification.

(C) Severity Level III --- Significant Violations.

(1) Health Physics.

(a) Single exposure of a worker in excess of 3 rems of radiation to the whole body, 7.5 rems to the skin of the whole body, or 18.75 rems to the feet, ankles, hands or forearms;

(b) A radiation level in an unrestricted area such that an individual could receive greater than 100 millirem in a one hour period or 500 millirem in a seven consecutive days;

(c) Failure to make a 24-hour notification as required by 105 CMR 120.281 or an immediate notification required by 105 CMR 120.282;

(d) Substantial potential for an exposure or release in excess of 105 CMR 120.200, whether or not such exposure or release occurs (*e.g.*, entry into high radiation areas, such as under reactor vessels or in the vicinity of exposed radiographic sources, without having performed an adequate survey, operation of a radiation facility with a nonfunctioning interlock system);

(e) Release of radioactive material to an unrestricted area in excess of the limits of 105 CMR 120.222;

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(f) Improper disposal of licensed material not covered in Severity Level I or II;
(g) Exposure of worker in restricted areas in excess of the limits of 105 CMR 120.212;
(h) Release for unrestricted use of contaminated or radioactive material or equipment which poses a realistic potential for significant exposure to members of the public, or which reflects a programmatic (rather than isolated) weakness in the radiation control program;
(i) Cumulative worker exposure above regulatory limits when such cumulative exposure reflects a programmatic, rather than an isolated weakness in radiation protection;
(j) Conduct of licensee activities by a technically unqualified person;
(k) Significant failure to control licensed material;
(l) Failure to use exposure reduction devices properly (*e.g*., collimators, filtration);
(m) For a fluoroscopic system where the maximum allowable tabletop exposure rate is 5 R/min., test values of greater than or equal to 7 R/min. (uncorrected), but less than 25 R/min. Correspondingly, for a maximum allowable rate of 10 R/min., test values of greater than or equal to 14 R/min. (uncorrected) but less than 25 R/min. are included.
(n) A radiographic x-ray system having positive beam limitation where the x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, is such that either the length or the width of the x-ray field differs from that of the image receptor by greater than 10% of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.
(o) Intraoral dental systems capable of operations in the above 50 kVp range for which the field size at the cone tip is greater than or equal to nine centimeters or which exhibit a minimum SSD less than 16 centimeters.
(p) Dental radiographic systems in which it is possible to produce x-rays with the timer in the zero or off position.
(q) Mammographic x-ray systems in which the edge of the x-ray field at the chest wall extends beyond the edges of the image receptor by more than 5% of the source to image receptor distance.
(r) Therapy systems which fail to maintain proper surveys, calibrations, spot checks or operating procedures.

(2) Transportation.
(a) Breach of package integrity;
(b) Surface contamination or external radiation levels in excess of, but less than a factor of five above Agency requirements that did not result from a breach of package integrity;
(c) Any noncompliance with labeling, placarding, shipping paper, packaging loading, or other requirements that could reasonably result in the following:
a. Improper identification of the type, quantity, or form of material;
b. Failure of the carrier or recipient to exercise adequate controls; or,
c. Substantial potential for personnel exposure or contamination, or improper transfer of material; or,
(d) Failure to make required initial notification associated with Severity Level III violations.

(3) Materials Operations.
(a) Failure to control access to licensed materials for radiation purposes as specified by Agency requirements;
(b) Possession or use of unauthorized equipment or materials in the conduct of licensee activities which degrades safety;
(c) Use of radioactive material on humans where such use is not authorized;
(d) Conduct of licensed activities by a technically unqualified person;
(e) Radiation levels, contamination levels, or releases that exceed the limits specified in the license; or,
(f) Medical therapeutic misadministrations.
(g) Failure to obtain appropriate Agency approval before moving to a new use and/or storage location.

(4) Miscellaneous Matters.
(a) An MFS not amounting to a Severity Level I or II violation; or,
(b) Deliberate falsification, or falsification by or with the knowledge of management of records which the Agency requires be kept that did not involve signification information.

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(5) Emergency Preparedness. Violations of lesser severity than Severity Level II violations.

(D) Severity Level IV -- Violations.

(1) Health Physics.

(a) Exposures in excess of the limits of 105 CMR 120.211 not constituting Severity Level I, II, or III violations;

(b) A radiation level in an unrestricted area such that an individual could receive greater than two millirem in a one-hour period or 100 millirem in any seven consecutive days;

(c) Failure to make a 30-day notification required by 105 CMR 120.283;

(d) Failure to make a follow-up written report as required by 105 CMR 120.281, 120.287 and 120.750; or,

(e) Any other matter that has more than minor safety or environmental significance.

(f) A capacitor storage radiographic system such that the standby radiation is greater than 3.0 mR/hr, but less than 25 mR/hr.

(g) Systems equipped with positive beam limiting devices which do not allow the field size to be reduced to a size less than that of the image receptor.

(h) Systems equipped with positive beam limiting devices which do not provide for an automatic return to PBL from a reduced field size.

(i) Mobile radiographic systems for which the minimum source to skin distance is less than 27.5 centimeters.

(j) Mammographic systems manufactured after October 1977 for which the edges of the x-ray field on the right or left sides extend beyond the edges of the image receptor. If manufactured prior to November 1977 and the edges of the x-ray field on either side extend beyond the edge of the image receptor by more than 5% of the SID.

(2) Transportation.

(a) Package selection of preparation requirements which do not result in a breach of package integrity or surface contamination or external radiation levels in excess of Agency requirements; or,

(b) Other violations that have more than minor safety or environmental significance.

(3) Material Operations.

(a) Failure to maintain patients hospitalized who have cobalt-60, cesium-137, or iridium-192 implants or to conduct required leakage or contamination tests, or to use properly calibrated equipment;

(b) Other violations that have more than minor safety or environmental significance; or,

(c) Failure to report medical diagnostic misadministrations.

(4) Miscellaneous Matters.

(a) A false statement caused by an inadvertent clerical or similar error involving information which, had it been available to the Agency and accurate at the time the information should have been submitted, would probably not have resulted in regulatory action or the Agency seeking additional information.

(b) Unless specified in a more severe category, changes in procedures or other conditions of a license or certificate of registration of which the Agency was not informed (*e.g.*, change of address, expiration of certificate of registration); or,

(5) Emergency Preparedness. Violations of lesser severity than Severity Level III violations.

(E) Severity Level V -- Minor Violations.

(1) Health Physics.

(a) For a fluoroscopic x-ray system where the maximum allowable tabletop exposure rate is 5 R/min., test values of greater than 5.0 R/min. (uncorrected), but less than 7.0 R/min. Correspondingly, if the maximum allowable tabletop exposure rate is 10 R/min., test values of greater than 10.0 R/min. (uncorrected) but less than 14.0 R/min. are included.

(b) Other violations that have minor safety or environmental significance.

(2) Transportation. Other violations that have minor safety or environmental significance.

(3) Materials Operations. Other violations that have minor safety or environmental significance.

(4) Miscellaneous Matters. Other violations that have minor safety or environmental significance.

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(5) Emergency Preparedness. Other violations that have minor safety or environmental significance.